National Grain and Feed Association

North American Export Grain Association, Inc.

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2002N-0276
Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period

The National Grain and Feed Association (NGFA) and the North American Export Grain Association (NAEGA) submit this joint statement in response to the Food and Drug Administration's notice, published in the April 14, 2004 ***Federal Register***, reopening the comment period "on a limited set of issues" concerning its facility registration interim final rule under the Bioterrorism Preparedness and Response Act of 2002.

The NGFA, established in 1896, consists of 1,000 member companies from all sectors of the grain, feed, processing and exporting business that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. The NGFA's membership includes country, terminal and export elevators; feed manufacturers; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also consists of 36 affiliated state and regional grain and feed associations, as well as two international affiliated associations. The NGFA also has established strategic alliances with the Pet Food Institute and the Grain Elevator and Processing Society.

NAEGA, established in 1912, is comprised of private and publicly owned companies and farmer-owned cooperatives involved in and providing services to the bulk grain and oilseed exporting industry. NAEGA member companies ship practically all of the bulk grains and oilseeds exported each year from the United States. The Association's mission is to promote and sustain the development of commercial export of grain and oilseed trade from the United States. NAEGA acts to accomplish this mission from its office in Washington D.C., and in markets throughout the world.

The NGFA and NAEGA are collocated and have a joint operating and services agreement.

The NGFA and NAEGA submitted extensive comments in April 2003 on FDA's proposed rule implementing the facility registration requirements of the Bioterrorism Preparedness and Response Act of 2002. We commend the agency for adopting many of our recommendations as part of the interim final rule.

We also commend FDA for reopening the comment period so that companies that operate U.S. and foreign facilities that are affected by the rule can provide input on experiences that have occurred in the aftermath of the close of the most recent comment period in October 2003. However, we strongly believe that the set of issues on which the agency is seeking comment with respect to the facility registration interim final rule – each of which is related to the impacts of the requirement that foreign facilities hire and retain a U.S. agent – is far too limited.

Specifically, we respectfully urge FDA to consider and address the following concerns related to the serious problems experienced by companies with respect to the agency's implementation of the facility registration requirement, and to rectify these matters. Our concerns relate to the significant problems experienced by the industry concerning the confirmation and validation notices being distributed by FDA to entities that register facilities.

We have raised these issues previously with FDA. But each of the concerns referenced herein have yet to be rectified. Ultimately, we believe that failure to address these matters will compromise the accuracy of the facility registration information, cause continued confusion and inefficiency among companies required to register, and ultimately undermine the congressionally intended purposes of the facility registration requirement.

1. **There is Confusion Over the Intent of Facility Registration Confirmation/ Validation Notices:** There is significant confusion among companies concerning the purpose and intent of the confirmation and validation notices they receive after registering facilities with the agency. Specifically, there is confusion among facilities as to whether the principal intent is to verify that the information about the facility and the contact information is correct, **OR** whether it is to verify whether the facility should or should not be registered. Much of the confusion has been caused by the "Agree" and "Disagree" boxes contained in the confirmation/validation notices, and the poor verbiage contained in the notices themselves.

   To rectify this problem, we strongly urge FDA to develop a notice to be posted on its web site and disseminated electronically to facility registrants that clarifies that the intent of the confirmation/validation notice is to verify that the information about the facility and the contact information is accurate. Further, we urge the agency to revise the wording of the confirmation/

validation notices to make that intent clear. We also believe the agency should suspend the issuance of any further such notices until the verbiage and format are revised. Our organizations, as well as others that have expressed similar concerns, would be pleased to work with the agency in revising the terminology used in the notices to enhance their clarity.

2. **Facility Confirmation/Validation Notices are Being Sent to Individual Facilities Rather than to the Preferred Mailing Addresses Designated by Companies:** In a web-site notice posted on Feb. 2, 2004, FDA acknowledged the discovery of a software error in the computer program used to transmit its confirmation/validation notices that caused such notices to be sent to the individual registered facilities rather than to the preferred mailing address designated by the company registering the facilities.

   The NGFA and NAEGA seek confirmation that this computer software deficiency has been corrected and that notices to newly registered facilities are being sent to the preferred mailing addresses designated by the company on the facility registration form. We also seek confirmation from the agency that notices returned to FDA as undelivered because the facility operates seasonally or is inactive, as well as for facilities that did not respond, will be resent to the preferred mailing address designated by the company. We also believe it would be advisable for FDA to send an "early alert" correspondence to companies' preferred mailing addresses informing them in advance that they will be receiving confirmation/validation notices for facilities they registered.

3. **Facility Confirmation/Validation Notices Contain Inaccurate Information:** We have received numerous examples of significant factual errors in the confirmation/validation notices being generated by FDA when compared to the information submitted by companies when initially registering their facilities. We understand from FDA that this has been caused in part by the frequent software changes necessary to expand its facility registration computer program capacity. The accuracy problems also have been caused by the fact that there are at least 15 different versions of the confirmation/validation notice, depending upon the facility being registered.

   The NGFA and NAEGA believe it is incumbent upon FDA to issue a notice on its web site and to the preferred mailing addresses of companies that have registered to alert them as to what should be done if a company receives a confirmation/validation notice containing inaccurate information. From discussions with FDA, it is our understanding that FDA wants the company to check the on-line version of the facility's registration in FDA's database to determine if it contains the accurate information and, if so, to disregard the inaccurate information contained in the confirmation/validation notice. But FDA has yet to make this clear to the regulated industries.

We also ask that FDA investigate problems our members have experienced concerning inaccurate information in the on-line version of the facility registration form. Specifically, several NGFA member companies that used the FDA on-line form to register electronically have found errors when rechecking their listings in FDA's on-line database, even though they had previously verified that the information was accurate at the time originally submitted.

4. **Companies with Registered Facilities Have Not Received Confirmation/ Validation Notices:** Some of our member companies have reported that they have not received confirmation/validation notices even though they registered facilities with FDA several months ago. This may be attributable to FDA suspending the issuance of such notices until problems such as those cited in these comments can be addressed. We ask that FDA investigate this matter.

5. **Facilities Seeking Assistance from FDA's Help Line Often Experience Difficulty in Obtaining Accurate Information:** It is our understanding that FDA has hired outside contractors to provide personnel to staff its bioterrorism regulation help line, and that these help-line personnel are limited in what they can say; in essence, they have "read-only" authority and are not in a position to be problem-solvers.

   The NGFA and NAEGA recognize that it may be impractical to designate a certain number of personnel to respond to specific questions related to the confirmation/validation notices. However, we do believe it is incumbent upon FDA to provide clear information to the regulated industries on the process that should be used if a party calling the help line does not obtain the information it needs. It is our understanding that in these situations, the party should ask for the "shift supervisor," each of whom is an FDA employee. We believe FDA should post information on its Bioterrorism web site, as well as the "escalation procedures" that outline the steps companies should take to contact the appropriate FDA officials if they are unable to obtain satisfactory information from the help line.

Finally, the NGFA and NAEGA have received periodic complaints about the accessibility and reliability of FDA's electronic facility registration system. There still are situations in which the system has been "down." As the "education/information" phase of FDA's implementation of the facility registration requirement comes to an end – and strict enforcement begins – it is imperative that FDA's on-line facility registration capabilities be reliable and constant. We urge the agency to make the necessary software improvements to ensure that occurs.

The NGFA and NAEGA appreciate this opportunity to provide our collective input on FDA's facility registration process under the Bioterrorism-Preparedness Act. We raise the aforementioned issues precisely because we are committed to enhancing the security of agricultural facilities and support reasonable, prudent steps that enable FDA to

better respond promptly and effectively to a threatened or actual terrorist attack on the U.S. food or feed supply, without imposing undue burdens or costs on the food and feed system.

We pledge our continued proactive efforts to work with our industry sectors and with government to further enhance the safety and security of the nation's food and feed supply.

Sincerely,

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Gary C. Martin
President
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